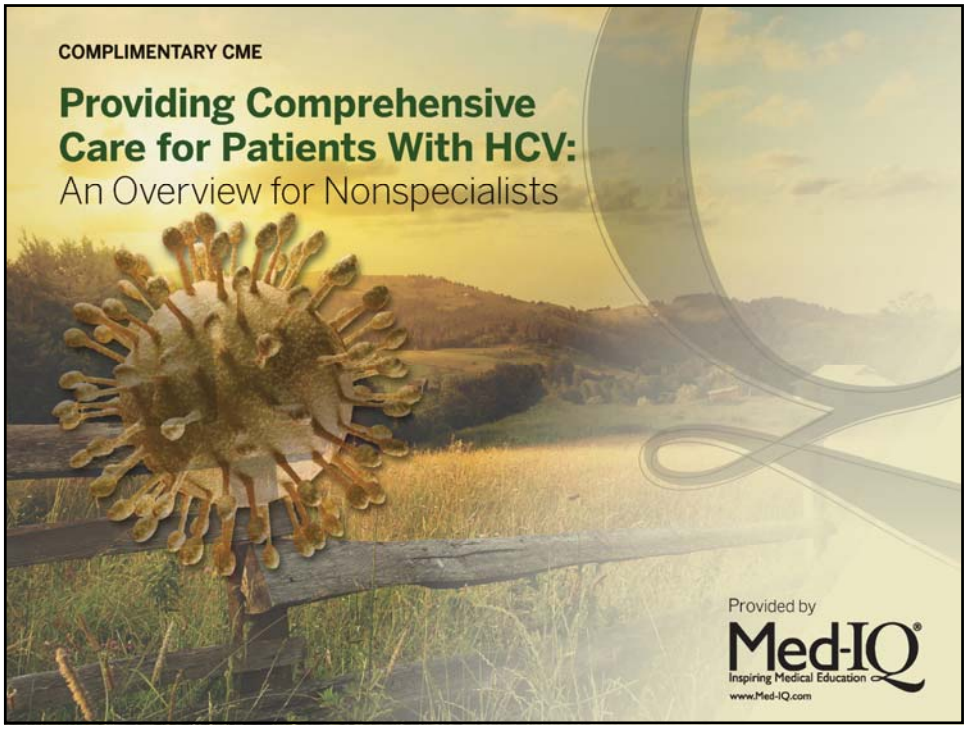


Learning Objectives

Upon completion, participants should be able to:

- Outline critical components of comprehensive care for patients with chronic HCV infection
- Counsel patients about reasonable expectations related to treatment monitoring requirements and treatment adherence

Transmission

- IDU-related transmission
  - IDU is the most commonly reported risk factor for new cases of HCV
  - Clear association with shared syringes and needles but also shared equipment used to prepare and inject drugs (eg, filtration cottons, drug cookers, rinse water)
- Sexual transmission
  - Risk is low but not zero
  - Unusual in monogamous heterosexual partners; having multiple partners is associated with increased risk
  - Higher among MSM, particularly those who are HIV positive
- Vertical transmission (mother to child)
  - Less common than in hepatitis B virus or HIV but does occur; transmission rate is 3%-10%
  - Major risk factor for transmission is HIV coinfection and detectable HCV viremia during pregnancy
- Household contacts
  - Transmission is possible through contact with blood (eg, open cuts or sores, sharing razors, nail clippers, toothbrushes, and any other items that can come into contact with blood)
  - HCV is NOT spread through casual contact or sharing food, water, or eating utensils
- Others
  - Intranasal drugs, tattoos, needlesticks

IDU = injection drug use;
MSM = men who have sex with men.

AASLD/IDSA. www.hcvguidelines.org; Benova L, et al. *Clin Infect Dis*. 2014;59:765-73.

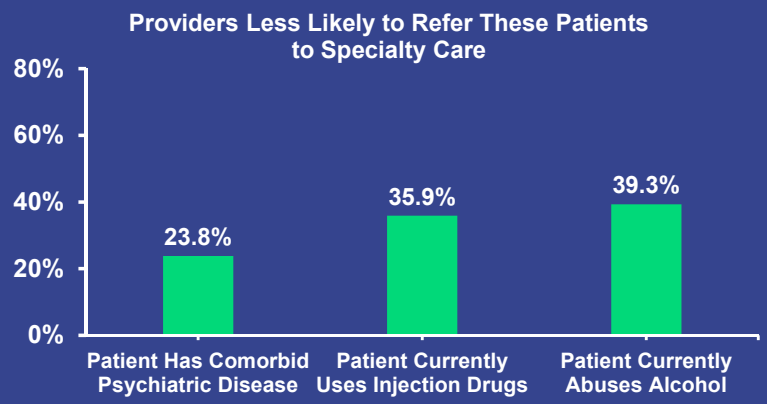
Transmission Counseling

- Substance abuse treatment
- For those who continue to use drugs:
  - Avoid sharing or reusing syringes, needles, water, cotton, and/or other drug-preparation equipment
  - Clean injection sites with new alcohol swab
  - Use safe, puncture-proof container for disposing needles and syringes
- Patients with HCV should not donate blood and should discuss HCV infection prior to donating organs, tissue, or semen
- Condoms are recommended for persons with multiple sex partners and those with HIV
- HCV can survive outside the body for at least 16 hours
  - Surfaces contaminated with blood should be cleaned using a dilution of 1 part household bleach to 9 parts water
  - Gloves should be worn when cleaning up blood spills

AASLD/IDSA. www.hcvguidelines.org.

HCV Treatment in PWID: Rural Provider Views

- 2016 survey of 323 rural-based clinicians in US



Med-IQ data on file.

HCV Treatment Considerations Among PWID

- Treatment is recommended for PWID with chronic HCV infection
- History of IDU and recent drug use at treatment initiation are not associated with reduced SVR
- The decision to initiate therapy should be based on availability of agents and disease characteristics
- DAA therapy does not require specific methadone and buprenorphine dose adjustment; monitor for signs of opioid toxicity or withdrawal
- PWID with ongoing social issues, history of psychiatric disease, and more frequent drug use during therapy have a risk of lower adherence; counsel on the importance of adherence
- Clinical management should include harm-reduction programs, social work, and social support services

DAA = direct-acting antiviral; SVR = sustained virologic response.

Grebely J, et al. *Inter J Drug Policy*. 2015;26:1028-38.

SVR Among Patients Receiving OST

Treatment	Study	Outcome	Adverse Events (Occurring in ≥ 10% of Patients)
Ombitasvir/ paritaprevir/R + dasabuvir + RBV	Phase 2, multicenter, open-label, single-arm study	• 97.4% of patients on OST achieved SVR12	• Fatigue, headache, nausea, pruritus, insomnia
Sofosbuvir/ velpatasvir	Post hoc analysis of ASTRAL trials	• 96% of patients on OST achieved SVR12 • SVR rate among patients on OST was similar to those not on OST • No difference in treatment completion, adherence, or safety among those receiving and not receiving OST	• Fatigue, headache, nausea, anemia
Ledipasvir/ sofosbuvir ± RBV	Post hoc analysis of ION trials	• 94% of patients on OST achieved SVR12 • No significant difference in SVR12 among those receiving and not receiving OST • No difference in treatment completion, adherence, or safety among those receiving and not receiving OST	• Fatigue, headache, nausea
Elbasvir/ grazoprevir	C-EDGE CO-STAR trial	• Drug use at start of treatment and during treatment did not affect SVR12 or treatment adherence • 91.5% of patients on OST achieved SVR12	• Fatigue, headache, nausea

OST = opioid-substitution therapy.

Lalezari J, et al. *J Hepatol*. 2015;63:364-9; Grebely J, et al. *Clin Infect Dis.* 2016;63:1479-81; Grebely J, et al. *Clin Infect Dis*. 2016;63:1405-11; Dore JG, et al. *Ann Intern Med*. 2016;165:625-34.

HCV Reinfection Following SVR: Considerations Among PWID

- Do not exclude HCV treatment based on perceived risk of reinfection
- After SVR, monitor for HCV reinfection annually among PWID with ongoing risk behavior
  - Reinfection rate is lower in PWID (approx. 2.4/100 person-years of observation) than general population of injection drug users (6.44/100 person-years of observation)
  - Reinfection rates increase with active/ongoing IDU
- Provide harm-reduction education and counseling to prevent HCV reinfection
- HCV treatment as prevention is a concept of great interest though is not yet studied in HCV

Grebely J, et al. *Inter J Drug Policy*. 2015;26:1028-38; Aspinall EJ, et al. *Clin Infect Dis.* 2013;57:S80-9.

Immunizations

- Hepatitis A virus
  - Screen for immunity
  - Vaccinate nonimmune patients
- Hepatitis B virus
  - Screen for immunity with HBsAB, HBcAB, and HBsAg
  - Vaccinate nonimmune patients
  - Recent FDA boxed warning requiring hepatitis B virus testing prior to DAA initiation based on risk of reactivation
- Pneumococcal vaccine
  - ACIP recommends 23-valent polysaccharide pneumococcal vaccine for all persons with chronic liver disease
  - If patient is younger than 65 years, administer second dose at age 65 (if at least 5 years have elapsed from initial vaccine)
- Usual adult vaccines
  - Annual influenza
  - Tdap or Td booster every 10 years

ACIP = Advisory Committee on Immunization Practices; FDA = Food and Drug Administration; Td = tetanus and diphtheria; Tdap = tetanus, diphtheria, and pertussis.

AASLD/IDSA. www.hcvguidelines.org; Kim DK, et al. *MMWR Morb Mortal Wkly Rep.* 2016;65:88-90.

Pregnancy and HCV Treatment

- For patients receiving ribavirin-containing regimens
  - Women treated with ribavirin should not become pregnant during or for 6 months after treatment
  - Men treated with ribavirin should be cautioned to prevent pregnancy during and for 6 months after treatment
- DAAs have not been tested in pregnancy; contraception counseling is recommended

AASLD/IDSA. www.hcvguidelines.org.

Testing for Children Born to HCV-Infected Mothers

- Antibody testing
  - Maternal HCV antibody is passively transferred to infant
  - Defer HCV antibody testing of infants until 18 months of age
- RNA testing
  - Can be conducted at 6 months of age

Alcohol Use Counseling

- There is no “safe” amount of alcohol consumption
- Correlation between excess alcohol use and development/ progression of liver fibrosis and development of HCC
- Assess alcohol use in all patients with HCV
  - AUDIT-C
  - National Institute of Alcohol Abuse and Alcoholism: http://pubs.niaaa.nih.gov/publications/Practitioner/CliniciansGuide2005/clinicians_guide.htm

AUDIT-C QUESTIONNAIRE

Patient Name_____ Date of Visit _____

1. **How often do you have a drink containing alcohol?**
   - ☐ a. Never
   - ☐ b. Monthly or less
   - ☐ c. 2-4 times a month
   - ☐ d. 2-3 times a week
   - ☐ e. 4 or more times a week
2. **How many standard drinks containing alcohol do you have on a typical day?**
   - ☐ a. 1 or 2
   - ☐ b. 3 or 4
   - ☐ c. 5 or 6
   - ☐ d. 7 to 9
   - ☐ e. 10 or more
3. **How often do you have six or more drinks on one occasion?**
   - ☐ a. Never
   - ☐ b. Less than monthly
   - ☐ c. Monthly
   - ☐ d. Weekly
   - ☐ e. Daily or almost daily

AASLD/IDSA. www.hcvguidelines.org;
SAMHSA. www.integration.samhsa.gov/images/res/tool_auditc.pdf.

Obesity Concerns

- Patients with underlying insulin resistance associated with obesity and metabolic syndrome have higher risk of fibrosis progression
- Counsel patients to maintain a healthy weight and follow liver-healthy diet
- Avoid/manage hyperlipidemia
  - Statin therapy is not contraindicated in patients with HCV
  - Be aware of drug-drug interactions with some statins and DAAs

AASLD/IDSA. www.hcvguidelines.org;
Lewis JH, et al. *Hepatology*. 2007;46:1453-63; www.hep-druginteractions.org.

Prior to Treatment Initiation

- New FDA boxed warning on all DAAs: risk of reactivating hepatitis B virus
- There is a serious risk for some patients who have been infected with hepatitis B virus and are being treated with DAAs
- Healthcare professionals should screen all patients for evidence of current or prior hepatitis B virus infection before starting treatment with DAAs and monitor patients using blood tests for hepatitis B virus flare-ups or reactivation during treatment and post-treatment follow-up
- For more information: www.fda.gov/Drugs/DrugSafety/ucm522932.htm

AASLD/IDSA. www.hcvguidelines.org.

Key Concepts in HCV Treatment Monitoring

- Real-world data show good adherence to HCV treatment
- 4 weeks after start of treatment
  - CBC, creatinine level, GFR, hepatic function
  - 10-fold increase in ALT at week 4 = treatment discontinuation or any increase with symptoms
- Quantitative HCV viral load testing
  - 4 weeks, 12 weeks post treatment (SVR12)
- Clinicians caring for patients with HCV who are not treatment prescribers have an important role in supporting adherence

ALT = alanine aminotransferase;
CBC = complete blood count; GFR = glomerular filtration rate.

AASLD/IDSA. www.hcvguidelines.org.

Comprehensive Care for Patients With HCV

- Reduction of transmission risk is critical
- PWID can be treated successfully
- Non-treaters can support patients with
  - Proper immunization
  - Adherence support
  - Alcohol use counseling
  - Maintenance of overall health

Questions

Audience Question:
What are your recommendations regarding the vaccine for shingles for patients with HCV?

Audience Question:
My patient with HCV who currently uses injection drugs but desires HCV treatment was denied coverage. Why?

Audience Question:
Isn't the length of treatment for genotype 1 patients with lower viral load only 8 weeks?

Audience Question:
How do you treat HCV when the genotype is indeterminate?

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